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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,061	12/15/1999	KEITH R. MCCRAE	6056-260	3290

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EXAMINER	
ROBINSON, HOPE A	

ART UNIT	PAPER NUMBER
1653	19

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/461,061	McCrae
Examiner	**Art Unit**
Hope Robinson	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 22, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8 and 12-48* is/are pending in the application.

4a) Of the above, claim(s) *8, 12-23, and 25-48* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-7 and 24* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4, 5, 6*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group I (claims 1-8, 12-24 and 46-48, SEQ ID NOS: 1-4) in Paper No. 18 is acknowledged. The traversal is on the ground(s) that "claim 1 defines a genus of pharmaceutical compositions comprising compounds which share the common core sequence SEQ ID NO:1. The peptides of SEQ ID NO: 9 (grouped ... in Group III) and SEQ ID NO: 10 (not grouped...in any pharmaceutical composition grouping) contain SEQ ID NO: 1". This argument is not convincing as the MPEP states that restriction requirement is proper if the inventions are distinct and independent, which means that the sequences although they have some similarities are distinct. Furthermore, applicant's contention that SEQ ID NO: 10 was not grouped by the examiner is incorrect as SEQ ID NO: 10 is a part of Group V in the restriction requirement. The applicant also argues about the grouping of claims having the core sequence of SEQ ID NO: 15, the same reasoning as applied to SEQ ID NO: 1 is applicable, as any change in residues within the sequence provides a structural difference, hence arguable, a separate protein with a different function. As the MPEP establishes that distinct (having a relationship) and independent (having no relationship) are criterions for restriction requirement, the restriction instituted in this application is deemed proper and made final.

Claim Disposition

2. Claims 46-48 have been added. Claims 1-8 and 12-48 are pending. Claims 8, 12-23 and 25-48 are withdrawn from consideration as directed to a non-elected subject matter. Claims 1-7 and 24 are under examination. With regard to claims 8, 12-24 and 46-48 that were elected, these claims do not recite the elected sequences, SEQ ID NOS: 1-4 and as applicant did not amend the claims in response to the restriction requirement to cancel the non-elected subject matter, these claims have been withdrawn from consideration. Regarding claims 6 and 7 these claims will only be examined in so-far-as they pertain to the elected subject matter (see for example claim 1 from which the claims depend).

3. The claims have been renumbered under Rule 1.126 as Amendment 16B, filed January 11, 2002 instructed the PTO to add claims 46, 48 and 49 instead of claims 46, 47 and 48. Thus, claim 48 has been renumbered as claim 47 and claim 49 has been renumbered as claim 48.

Information Disclosure Statement

4. The information disclosure statement filed on 12/15/99 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because there are items listed on the information disclosure statement that are missing from the application. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. A line has been drawn through the following items on the information disclosure statement: AE, AF, AH, AJ, AK and AL.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabled for the composition comprising SEQ ID NOS: 1-4, does not reasonably provide for any fragment thereof as claimed. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does

not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to:

I. Quantity of Experimentation Necessary:

The claimed invention is directed to a composition comprising SEQ ID NOS: 1-4 and fragments thereof (in particular claim 3 recites an " N-terminal truncation fragment thereof and a C-terminal truncation fragment thereof with regard to SEQ ID NOS: 2 and 3). The claims have no functional limitation as to a use for the claimed composition, therefore, one skilled in the art would have to engage in undue experimentation to determine if the fragment has the activity set forth in the disclosure (see for example page 4, for "anti-angiogenic activity"), see claims 1-7. Note that the specification does not provide a definition or any details regarding the characteristics or properties of the claimed fragment. Further, the specification does not exemplify the claimed fragment in association with a disease or in a bioassay.

II. Amount of direction or guidance presented:

The specification does not disclose one reasonable method for making and using the invention that bears a reasonable correlation to the entire scope of the claim, as the specification lacks guidance/direction as to attributes of the claimed fragment, i.e., size, structure and function. It is noted that page 13 of the specification indicates that "the N-terminal and C-terminal truncation fragment" is described as being a fragment obtained from a parent sequence by

removing one or more amino acids from these terminals. However, this definition does not breathe life into the claim as the discussion is more exemplary than limiting. Further, no guidance is provided as to which one or more amino acids are removed from the terminals and in what positions. Thus, one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims.

III. Presence or absence of working examples:

The working examples provided do not demonstrate the claimed fragment in association with the claimed invention.

IV. Nature of the Invention:

The nature of the invention a composition comprising fragments thereof of the claimed compound. However, the specification does not provide sufficient guidance/direction to enable the full scope of the claimed invention as no special features/characteristics of the claimed fragments, such as size, length or biological activity is described or demonstrated in the present specification.

V. State of the prior art and Relative skill of those in the art:

The general knowledge provided in the prior art is insufficient as specific teaching is required to be able to practice the full scope of the claimed invention.

VI. Predictability or unpredictability of the art:

Since very little is known in the prior art about the nature of the invention renders the art unpredictable. The specification should then give more details as to how to make and use the invention in order to be enabling. As fragments of the compounds are claimed in the present application the claim encompasses a genus that is highly variable.

VII. Breadth of the claims:

The breadth of the claim is very broad and encompass an unspecified amount of fragments which are not adequately described or demonstrated in the specification.

Thus, the specification contemplates but does not exemplify any functional fragments of the protein. Furthermore, there is no demonstration of the claimed protein fragment in a therapy or medicament or assay. No description of the fragments is provided. Furthermore, the claims encompass an unspecified amount of fragments. In view of the foregoing, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 6-7 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 are indefinite because the claims recite non-elected subject matter, therefore, does not particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is indefinite because the claim depends from a rejected based claim.

Art of *Record*

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Schmaier et al. (U.S. Patent No. 6,143,719, November 7, 2000). Schmaier teach the sequence set forth in SEQ ID NO: 3, however, only teaches a portion of the sequence contained in SEQ ID NO: 1, in the instant application.

Auerswald et al. (FEBS, vol. 321, no. 1, pages 93-97, 1993). Auerswald teach the sequences contained in SEQ ID NOs: 1 and 4 of the instant application (see Figure 3 of the reference). However, the sequence disclosed by Auerswald that is identical to SEQ ID NO: 1 of the application, has an X_1 and X_2 that exceeds the range of zero to 12 amino acid as required by the claim (see claim 1).

Conclusion

8. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Hope A. Robinson whose telephone number is (703)308-6231. The Examiner can normally be reached on Monday - Friday from 9:00 A.M. to 5:30 P.M. (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor Christopher S.F. Low, can be reached at (703)308-2932.

Any inquiries of a general nature relating to this application should be directed to the Group Receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. The official fax phone number for Technology Center 1600 is (703) 308-2742. Please affix the Examiner's

name on a cover sheet attached to your communication should you choose to fax your response. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Hope A. Robinson, MS

Patent Examiner

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER